



Pfizer Global Regulatory Affairs
Pfizer Inc.
235 East 42nd Street/New York, NY 10017-5755

Global Product Development

09 April 2021

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

THIS DOCUMENT CONTAINS CONFIDENTIAL AND/OR TRADE SECRET INFORMATION THAT IS DISCLOSED ONLY IN CONNECTION WITH THE LICENSING AND/OR REGISTRATION OF PRODUCTS FOR PFIZER INC OR ITS AFFILIATED COMPANIES. THIS DOCUMENT SHOULD NOT BE DISCLOSED OR USED, IN WHOLE OR IN PART, FOR ANY OTHER PURPOSE WITHOUT THE PRIOR WRITTEN CONSENT OF PFIZER INC.

Re: Amendment to Emergency Use Authorization (EUA) 27034 – Emergency Authorization for Individuals 12-15 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Dear Dr. Gruber,

Reference is made to the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine (BNT162/PF-07302048) issued on 11 December 2020. The authorized indication is active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Pfizer is hereby submitting an Amendment to EUA 27034 to extend the emergency use authorization to individuals 12-15 years of age. The proposed indication is active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals **12** years of age and older.

The data presented in this EUA amendment from pivotal study C4591001 (conducted under BB-IND 19736) support the use of Pfizer-BioNTech COVID-19 Vaccine in individuals 12-15 years of age based on noninferiority of the immune response measured by SARS-CoV-2 neutralizing antibody titers in this adolescent group compared to young adults 16-25 years of age, which serves as immunobridging for adolescents; efficacy data in the 12-15 years of age group; and safety data in approximately 2200 adolescents with a median follow-up time of at least 2 months after Dose 2. Additionally, safety data in adolescents are compared to the larger data safety data set of individuals 16-55 years of age. These data support that the known and potential benefits of the vaccine outweigh the known and potential risks.

Also, as requested by the Agency via email on 31 March 2021, clinical safety and efficacy data have been populated into the respective shell tables in the Agency-provided template. A [Response to the 31 March 2021 Request](#), which includes additional information and clarifications to explain certain necessary adjustments to the templates provided by CBER, is provided in Module 1.11.3. The tables are provided in both [Microsoft Word](#) (508-compliant) and [PDF](#) formats in Module 5.3.5.1.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 212-733-2613; via facsimile at 845-474-3500; or via e-mail at neda.aghajanimemar@pfizer.com.

Sincerely,

Neda Aghajani Memar, Pharm.D.
Director
Pfizer Global Regulatory Affairs

CC: Ramachandra S. Naik, Ph.D.
CC: Laura Gottschalk, Ph.D.